SECTION 5
510(k) SUMMARY

510(k) Notification K K130752

GENERAL INFORMATION

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AUG 15 2013

Contact Person:
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Date Prepared: August 14, 2013

DEVICE INFORMATION

Trade Name:
DynaSense System

Generic/Common Name:
Bed-patient monitor

Classification:
21 CFR§880.2400, Bed-patient monitor, Class I

Product Code:
KMI, Monitor, Bed Patient

PREDICATE DEVICE(S)

- Wireless MedCARE VivaTRAK™ System (K101109)
- AFrame Digital MobileCare Monitor™ (K090138)

INDICATIONS FOR USE

DynaSense monitors orientation and activity of patients susceptible to pressure ulcers. It allows healthcare providers to implement individualized turn management plans and continuously monitor each patient. DynaSense provides alerts when patient orientation or activity deviates from parameters set by healthcare providers. The device is intended for use in medical, nursing and long-term care facilities including independent living, assisted living and rehabilitation facilities.

DEVICE DESCRIPTION

DynaSense is a patient monitoring system that has been designed for use in hospitals, nursing homes, or other patient care facilities to aid standard care procedures for patients who are susceptible to pressure ulcers. The system monitors and reports patient activity and orientation as well as alerts the user (i.e., healthcare provider) when activity levels deviate from parameters set by healthcare providers. DynaSense is comprised of Patient Sensors, Relay Antennas, a USB RF Transceiver, Mesh Network Server Software, and User Interface software.

Each Patient Sensor is associated with a single patient, such that the patient's orientation and activity can be monitored. Data collected by the Patient Sensor is automatically communicated wirelessly to a nearby Relay Antenna, which subsequently relays these data to be displayed on the User Interface and maintained in a database. The system's Relay Antennas that are plugged into electrical outlets on the walls of the facility and the USB RF Transceiver that is plugged into the computer, on which the Mesh Network Server Software is installed or accessed, form a wireless network that allows data to be transmitted for display. The Mesh Network Server Software manages this network of Relay Antennas and USB RF Transceiver and collects the data from the Patient Sensors to allow monitoring of multiple patients on a single screen within the User Interface.

SUBSTANTIAL EQUIVALENCE

The indications for use for the predicate devices are substantially equivalent to the proposed indications for use for DynaSense. DynaSense has the same intended use and similar technological characteristics as those of the predicate devices, the VivaTRAK System (K101109) and the MobileCare Monitor (K090138). Any differences in the technological characteristics between the devices do not raise any new issues of safety or effectiveness. Thus, DynaSense is substantially equivalent to the predicate devices.

TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

Performance testing was conducted on DynaSense to support a determination of substantial equivalence to the predicate devices. The testing included the design verification (e.g., software verification), Electrical Safety, and Electromagnetic Compatibility testing. The collective results of the testing demonstrate that the chosen materials, the manufacturing processes, and design of DynaSense meet the established specifications necessary for consistent performance during its intended use. In addition, the

collective testing results demonstrated that DynaSense does not raise new questions of safety or effectiveness for monitoring patient activity when compared to the predicate devices.

CONCLUSION

DynaSense is a patient activity monitoring system, which provides the user with the patient's orientation and preset monitoring alerts. DynaSense has the same intended use and similar technological characteristics as those of the predicate devices, the VivaTRAK System and the MobileCare Monitor. Furthermore, device safety and performance testing have demonstrated that the device performs as intended in its intended use environment. As such, DynaSense is substantially equivalent to the predicate devices.

SUMMARY

DynaSense is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 15, 2013

Centauri Medical, Incorporated
C/O Lori Adels, Ph.D.
Executive Vice President, Regulatory Affairs
Experien Group, Limited Liability Company
755 North Mathilda Avenue, Suite 100
Sunnyvale, CA 94085

Re: K130752
Trade/Device Name: DynaSense System
Regulation Number: 21 CFR 880.2400
Regulation Name: Bed-Patient Monitor
Regulatory Class: I
Product Code: KMI
Dated: July 3, 2013
Received: July 5, 2013

Dear Dr. Adels:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Kwame Ulmer, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4
INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K130752

Device Name: DynaSense System

Indications For Use:

DynaSense monitors orientation and activity of patients susceptible to pressure ulcers. It allows healthcare providers to implement individualized turn management plans and continuously monitor each patient. DynaSense provides alerts when patient orientation or activity deviates from parameters set by healthcare providers. The device is intended for use in medical, nursing and long-term care facilities including independent living, assisted living and rehabilitation facilities.

Prescription Use _X_ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use _____ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C. Chapman
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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Respiratory, Infection Control and
Dental Devices
510(k) Number: K130752